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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
DIRAMIO, JACQUELINE A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/584,484

Applicant(s)

BRANDER ET AL.

Examiner

JACQUELINE DIRAMIO

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12 and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. Applicant's amendments to claim 1 and cancellation of claim 8 are acknowledged.
2. Currently, claims 1 – 7, 9 – 13 and 17 – 19 are pending. Claims 1 – 7, 9 – 12 and 17 – 19 are under examination; claim 13 is acknowledged as withdrawn as drawn to a non-elected invention.

Withdrawn Objections and Rejections

3. All previous objections to the drawings and specification are withdrawn in view of Applicant's amendments filed March 8, 2010.
4. All previous rejections of the claims under 35 U.S.C. 102 and 103 are withdrawn in view of Applicant's amendments and arguments filed March 8, 2010.

Response to Arguments

5. Applicant's arguments, see pages 10-13, filed March 8, 2010, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 102 as being anticipated by Freeman et al. (US 2003/0104521) have been fully considered and are persuasive. In particular, Applicant's argument that Freeman et al. fail to teach the amendment to claim 1, which was previously recited in dependent claim 8 and requires the biologically effective layer to comprise a biomembrane isolated from either prokaryotic or eukaryotic cells, wherein the layer is a lipid

bilayer, is found persuasive given that Freeman et al. only teach the inclusion of a “synthetic” or “artificial lipid bilayer” (see paragraph [0034]). Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 4, 5, 7, 9 – 12 and 17 – 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al. (US 2005/0230272).

Lee et al. teach a porous biosensing device (assay chip) for investigation of a functionality of non-lipid molecules and their interactions with molecules, comprising:

- a) a nanopore substrate having a plurality of nanopores;
- b) a substantially planar polymeric (support) layer 14 deposited on said nanopore substrate and having a plurality of nanopores corresponding to said nanopores of said nanopore substrate;
- c) a biologically effective membrane layer configured to host at least one of a non-lipid molecule and functional molecule, deposited on said polymeric layer and covering the plurality of nanopores, resulting in accessible nanopores from both sides of the biologically effective

membrane layer for measurements, wherein the biologically effective membrane layer is a biomembrane isolated from one of prokaryotic and eukaryotic cells, and wherein the biologically effective membrane layer is a lipid bilayer that is formed by preparation and later fusion of lipid vesicles (see Figures 1A, 1B, 3, and 6; paragraphs [0006]-[0008], [0033]-[0038], [0046]-[0048], [0051], [0052]-[0059], [0067], and [0074]; and Example 1).

With respect to Applicant's claim 2, a surface of the polymeric (support) layer can be chemically modified by at least one of hydrophobic and hydrophilic silanes resulting in a support promotion layer (see paragraph [0067]).

With respect to Applicant's claims 4, 5, 7, and 17 – 19, the diameter of the nanopores is from 1 – 500 nm and/or 400 - 600 microns resulting in an aspect ratio of 0.5 to 100 with respect to the thickness of the substrate, wherein said nanopores have a distance from each other in the range of 0.5 to 2000 times their diameter (see Figures 10 - 12; and paragraphs [0038], [0040], [0078], and [0090]).

With respect to Applicant's claims 9 – 12, the non-lipid molecules can be from a natural source such as eukaryotes or prokaryotes; or comprise a synthetic compound; or the functional molecule can be produced by recombinant DNA or RNA technologies; or the biologically effective membrane layer can be made from at least one intact living cells (see paragraphs [0033], [0046]-[0048], [0052]-[0061], [0071], [0074]; and Example 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.

(US 2005/0230272) in view of Heath et al. (US 2004/0120854).

The Lee et al. reference, which was discussed in the 102(e) rejection above, fails to teach that the polymeric (support) layer is either silicon nitride or silicon oxide, wherein the substrate comprises silicon or carbon containing materials, polymers, metals, dielectrics, glass and ceramics.

Heath et al. teach a semi-conductor wafer based device that is used to suspend biological materials, including lipid bilayers or single cells, for chemical, electrical and/or optical examination. The wafers have at least one nano- or micron-sized pore that extends therethrough, wherein the lipid bilayer or cell is suspended within the pore. The device preferably comprises a silicon oxide insulating layer (support layer) that is grown over a silicon wafer (substrate). The use of a silicon oxide insulating layer that is grown over a silicon wafer (i) achieves electrical isolation of the front and back sides of the wafer from each other; (ii) enables the co-fabrication of electronics on the same wafer platform; (iii) enables the preparation of many devices on a

single wafer for combinatorial measurement approaches; and (iv) enables the custom chemical modification of the wafer surface to promote adhesion of either the membranes or single cells (see Abstract; Figures 3-5; and paragraphs [0023], [0024], and [0035]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the device of Lee et al. to comprise a silicon substrate with a silicon oxide insulating (polymer) layer as taught by Heath et al. because Heath et al. teach the benefit of preparing a wafer based device comprising at least one pore and for use in suspending biological materials, including lipid bilayers, with a silicon oxide insulating layer that is grown over a silicon wafer because this type of wafer (i) achieves electrical isolation of the front and back sides of the wafer from each other; (ii) enables the co-fabrication of electronics on the same wafer platform; (iii) enables the preparation of many devices on a single wafer for combinatorial measurement approaches; and (iv) enables the custom chemical modification of the wafer surface to promote adhesion of either the membranes or single cells.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2005/0230272) in view of Beattie (US 5,843,767).

Lee et al. further fail to teach that the nanopores are arranged as sections with a particular area on a membrane of a particular area.

Beattie teaches a microfabricated, flowthrough porous apparatus for detecting binding reactions, wherein the apparatus comprises a porous silicon wafer (substrate) with integral sample wells. The pores or nanochannels of the silicon wafer are developed within regions on the wafer with specific nanochannel diameters, densities of the regions, and center-to-center

spacing between the nanochannels. By determining optimal diameters, density, and center-to-center spacing, a high density array of nanochannels is created on the wafer, which further yields a high surface area to volume ratio to tether various biomolecules to the nanoporous supports or wafers (see Figures 1A, 1B, and 3; Abstract; column 5, lines 28-67; and column 6, lines 1-14; and Examples 1-3).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Lee et al. specific densities of the nanopore regions and/or center-to-center spacing between the nanopores as taught by Beattie because Beattie teaches the benefit of determining optimal diameters, density, and center-to-center spacing of nanopores or nanochannels provided on a substrate in order to create a high density array of nanochannels on the substrate, which further yields a high surface area to volume ratio to tether various biomolecules to the nanoporous supports or wafers.

Conclusion

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

4/29/10

